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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,011	12/05/2001	Eric Douglas Bastian	006038.00002	3038

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,011

Applicant(s)

BASTIAN ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed March 16, 2004 has been received and entered into the case. Claims 8 – 15 are canceled; claims 1 – 17 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 7 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for treating a number of disorders comprising administering an effective amount of milk mineral. The specification fails to set forth method steps that would enable one in the art to practice the claimed method. Specifically, there is no guidance to one in the art how much milk mineral to administer, how often to administer it, or even how long one must endure the treatment. While the specification does set forth food products comprising milk mineral, the specification does not enable one in the art to use these products in a method for treating any of the claimed disorders. It would place undue burden of

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experimentation on a person in the art to find suitable treatment methods to the wide ranging classes of disorders, especially since there is not even a starting point for any of the claimed disorders. In addition, the specification lacks examples of methods for treating any of the claimed disorders, thereby failing to indicate any evidence of success.

Applicant argues that examples of food products are provided with amounts of milk mineral and that all of the disorders are related. Applicant additionally argues that there is no objective evidence that the claims are not enabled.

However, these arguments fail to persuade because the composition itself is not claimed, but a method of treating a number of disorders is claimed. The specification fails to set forth any method steps of treating any of the claimed disorders, with no guidance as to how much, how often or how long the treatment method requires. Regarding the relationship of the disorders, one in the art would not immediately recognize the overlap of treatments relative to the wide ranging disorders claimed. Specifically, one in the art would not recognize the variation and application in treatments of cancer, depression, migraines and/or heart failure, without undue experimentation.

Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1 – 3 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Govers.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The milk mineral comprises 60 – 90% mineral, 15 – 30% calcium, 7 – 17% phosphorous, 0 – 15% lactose, 5 – 15% protein, 0 – 5% fat and the food product comprises about 0.1 – 10% of milk mineral.

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Govers teaches administering milk mineral to inhibit colon cancer (abstract) wherein the milk mineral contains 178 mmol/kg calcium, 175 mmol/kg phosphorous, magnesium, potassium, fat and 14% protein (p.95, Materials and Methods).

The reference anticipates the claimed subject matter.

Applicant argues that Govers teaches away from treating with milk mineral and that Govers does not teach a food product with milk mineral.

However, these arguments fail to persuade because Govers does teach the method of administering milk mineral to treat colon cancer. In addition, Gover specifically teaches administering the milk mineral in powdered skim milk, which is a food product. Therefore the claims stand rejected.

5. Claims 1, 3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsubori.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum

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depression, or hypertensive disorders of pregnancy. The food product comprises about 0.1 – 10% of milk mineral.

Mitsubori teaches methods for treating hypertension by administering a whey milk mineral diet (abstract) wherein the milk mineral contains potassium, calcium, magnesium and phosphorous (p.94, Materials and Methods).

The reference anticipates the claimed subject matter.

Applicant argues that Mitsubori does not teach a milk mineral, but whey mineral.

However, this argument fails to persuade because applicant specifically defines “milk mineral” to mean “a mineral complex from whey or milk” (specification page 4). As such, Mitsubori teaches the claimed invention. Therefore the claims stand rejected.

6. Claims 1, 3 – 4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Howard.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone,

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colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products and comprises about 0.1 – 10% of milk mineral.

Howard teaches methods for treating obesity comprising administering supplements comprising dried skimmed milk, potassium, magnesium, phosphorous, zinc (abstract), and protein (col.1 line 5-35). The compositions are made into beverages or milk beverages (dairy products) (col.11 line 1-15, examples).

The reference anticipates the claimed subject matter.

Applicant argues that Howard does not teach milk mineral or a food product.

However, these arguments fail to persuade because the claimed method reads on treating the disorders by drinking milk (a food product comprising milk mineral). Howard specifically teaches food products such as beverages and milk (abstract, examples). Therefore the claims stand rejected.

7. Claims 1 and 3 – 7 stand rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Girsh.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes,

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depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products, specifically an acidic juice product, more specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Girsh teaches methods of administering compositions of milk or whey permeate, rich in vitamins and minerals, combined with flavoring agents to form beverages (abstract, examples). The compositions contain potassium (0059), calcium, magnesium, and phosphorous (0062). The flavoring agent may be orange juice (0065).

Since applicant defines treatment to include treating the disorder as well as prophylactic treatment, the reference anticipates the claimed subject matter.

Applicant argues that Girsh does not teach milk mineral, but whey permeate, and that Girsh does not recognize the method is useful for treating the claimed disorders.

However, these arguments fail to persuade because applicant specifically defines “milk mineral” to mean “a mineral complex from whey or milk” (specification page 4). In addition, applicant specifically defines treatment to include prophylactic treatment. As such, the claims are interpreted to include a method of preventing the claimed disorders by administering a food

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product comprising effective amounts of milk mineral. Since Girsh teaches the same step of administering food products with effective amounts of milk mineral, the method must also prevent the claimed disorders. Moreover, by practicing the methods of Girsh, one would inherently be preventing the claimed disorders. Therefore, the claims stand rejected.

8. Claims 1 and 3 – 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high energy bars, confectionary products, dairy products or bakery products, specifically an acidic juice product, more specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Nakagawa teaches a milk mineral composition comprising lactose, potassium, calcium, magnesium, zinc and phosphorous (col.2 line 16-24). The milk mineral is added to drinks such

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as orange juice in amounts of about 0.01 – 10% (col.2 line35-40) and is administered for dietary consumption (examples).

Since applicant defines treatment to include treating the disorder as well as prophylactic treatment, the reference anticipates the claimed subject matter.

Applicant argues that Nakagawa does not recognize the method is useful for treating the claimed disorders.

However, these arguments fail to persuade because applicant specifically defines treatment to include prophylactic treatment. As such, the claims are interpreted to include a method of preventing the claimed disorders by administering a food product comprising effective amounts of milk mineral. Since Nakagawa teaches the same step of administering food products with effective amounts of milk mineral, the method must also prevent the claimed disorders. Moreover, by practicing the methods of Nakagawa, one would inherently be preventing the claimed disorders. Therefore, the claims stand rejected.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Govers, Mitsubori or Howard in view of Girsh and/or Nakagawa.

Applicant claims a method for treating a disorder selected from high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, hypertensive disorders of pregnancy, type 2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolaemia, congestive heart failure, or immune deficiency; the method comprising administering a food product with an effective amount of milk mineral to an individual in need thereof. Specifically one of high blood pressure, stroke, obesity, kidney stone, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, or hypertensive disorders of pregnancy. The milk mineral comprises 60 – 90% mineral, 15 – 30% calcium, 7 – 17% phosphorous, 0 – 15% lactose, 5 – 15% protein, 0 – 5% fat. The food product is selected from acidic juices, acidic beverages, neutral pH beverages, high

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energy bars, confectionary products, dairy products or bakery products; is an acidic juice product, specifically orange juice. The food product comprises about 0.1 – 10% of milk mineral.

Govers teaches administering milk mineral to inhibit colon cancer (abstract) wherein the milk mineral contains 178 mmol/kg calcium, 175 mmol/kg phosphorous, magnesium, potassium, fat and 14% protein (p.95, Materials and Methods).

Mitsubori teaches methods for treating hypertension by administering whey milk mineral (abstract) wherein the milk mineral contains potassium, calcium, magnesium and phosphorous (p.94, Materials and Methods).

Howard teaches methods for treating obesity (col.1 line 15-35) comprising administering supplements comprising dried skimmed milk, potassium, magnesium, phosphorous, zinc (abstract), and protein (col.1 line15-35). The compositions are made into beverages or milk beverages (dairy products) (col.11 line 1-15, examples).

The references do not teach the methods wherein the compositions comprise the specific percents as claimed, or wherein they are incorporated into food products, specifically orange juice at 0.1 – 10%. However, at the time of the claimed invention, milk mineral were routinely incorporated into such food products. In support, Girsh teaches compositions of milk or whey permeate, rich in vitamins and minerals such as potassium, calcium, magnesium, and phosphorous (0059,0062), combined with orange juice (0065) to form beverages (abstract). In addition, Nakagawa teaches a milk mineral composition comprising lactose, potassium, calcium, magnesium, zinc and phosphorous (col.2 line 16-24) which is added to drinks such as orange juice in amounts of about 0.01 – 10% (col.2 line35-40). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to incorporate the compositions of

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Govers, Mitsubori and/or Howard into food products since it was a well known process as evidenced by Girsh and Nakagawa. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Girsh and/or Nakagawa to incorporate the compositions of Govers, Mitsubori and/or Howard into food products, with a reasonable expectation for successfully treating colon cancer, hypertension and/or diabetes.

Applicant does not set forth arguments relative to the above rejection. Therefore the claims stand rejected.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1 – 7 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 – 34 of copending Application No. 10/371,534. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the reference application claims a method for treating obesity comprising administering a composition comprising milk mineral and protein. It would have been obvious to one in the art to treat obesity comprising administering a composition containing milk mineral, as claimed by the reference application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

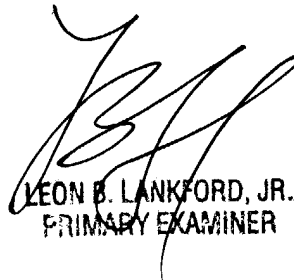
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
May 7, 2004.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER